practitioners of ordinary skill in the art, and requests that the claims be allowed, and the application proceed to patent grant.

#### **OVERVIEW OF AMENDMENTS & REMARKS**

- 1. SPECIFICATION: No amendments.
- 2. CLAIMS STATUS:
  - a. No claims are allowed:
  - b. No canceled claims.
  - c. Amended claims: 1, 4, 5 & 7.
  - d. No new claims:
  - e. Total (20) patent claims presented:
    - 1. (4) independent claims: 1, 4, 5 & 7.
    - 2. (16) dependent claims: 6 & 8 22.
- 3. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 FIRST PARAGRAPH.
- 4. AMENDMENT OF CLAIMS IN RESONSE TO REJECTION OF CLAIMS UNDER 35 USC SECTION 112 SECOND PARAGRAPH.
- 5. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 102.

### Attachments: (none)

- 6. FEE PAYMENT(S): NONE
- 7. FEE STATUS: (small entity) A total of \$480 has now been paid on the present application per this AMENDMENT E which now presents (4) independent claims, and (16) dependent claim for a total of (20) claims.

| BASIC NATIONAL FEE                         | \$375 |
|--|-------|
| EXCESS CLAIM FEES: (1) Independent (above) | \$105 |

8. REQUEST FOR CONSTRUCTIVE ASSISTANCE
Applicant has made diligent effort to write the claims of this application in allowable condition. If for any reason the claims are not believed to be in full condition for allowance, Applicant respectfully requests the constructive

assistance of Examiner pursuant to MPEP 707.07(j), and 706.03(d) in order that this application be placed in allowable condition as soon as possible.

#### **REMARKS**

# 3. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 FIRST PARAGRAPH.

Claims 1, 4 & 7 were rejected as failing to comply with the written description requirement, as the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

This rejection is yet again traversed.

Examiner asserts that the specification fails to provide sufficient written basis to claim an entire species within the broad claim terminology "...infectious diseases caused by drug-resistant strains of bacteria, bacterial infections in a human or animal host, solvent extraction of a component of a pepper plant" on the basis of discovery of one type of solvent extraction of pepper to treat one type of infectious disease caused by a drug-resistant strain of bacterial.

First of all, the Examiner "one type" assertions in the above are in error.

It is clear from the specification that the pepper compounds are broadspectrum antimicrobials among other things. The specification has disclosed other therapeutic properties of these same compounds beyond antibacterial, and has incorporated by reference other patents, which also disclose broadspectrum antimicrobial properties to include antifungal properties and wart treatment. See Abstract (p.19), Specification (p. 5.3.).

The instant specification further discloses more than seven specific cases, and referenced several other cases having been successfully treated with extracts of differing pepper plant species, differing solvents, and differing conditions, all with an astounding, and unprecedented level of effectiveness as compared to what practitioners of the art might expect with prior art treatments.

Clinical demonstrations of extracts of red pepper, black pepper, ginger, paprika,

and isolated capsaicin using water, alcohol (ethanol, isopropal), acetone, pure oleoresin and others used separately and in combination against an array of microbes and types of microbial infection are found within the specification.

As such, Applicant asserts that the specification provides sufficient representative species to claim any genus as to plant source, type of solvent for extraction, and type of bacterial infection being treated, and that the inventor was in possession of the claimed invention as of the filing of the application.

As such, all rejection of the claims 1, 4, and 7 as to failure of the specification to comply with the written description requirement is not proper and should be withdrawn with allowance of the claims 1, 4, and 7 along with their appended dependant claims.

The patent specification is explicit as to specific formulations used in actual case studies.

A person skilled in the art is thereby enabled to both produce, and apply any of the formulations toward the treatment of diseases as specifically described, or to those related.

Beginning with production of a crude extract of pepper; a very simple, quick, and inexpensive procedure, a practitioner is at once well equipped with a remarkably effective medical treatment that is broad-spectrum in nature. From there, a practitioner has the further option of isolation or refinement of chemical components of the extract in order to optimize use toward more specific conditions, if so desired.

FURTHER STILL, it is important to note that the terms and phraseology at issue: "...infectious diseases caused by drug-resistant strains of bacteria, bacterial infections in a human or animal host, solvent extraction of a component of a pepper plant" found in the claim preamble serve to define to practitioners of the art the scope or field(s) encompassed, and are not unique to the instant invention.

Herbalists, organic chemists, drug discovery scientists, and pharmacologists ect. easily understand what a "... solvent extraction of a component of a pepper plant..." entails in view of the written disclosure of the instant invention.

Physicians, Veterinarians, and their associated technicians understand what a bacterial infection is in a patient (host). They further understand that when

such a patient (whether human or animal) does not respond adequately to (other art) drug treatment for such a bacterial infection, that the possibility exists that the particular strain of bacteria causing the disease is for some reason able to resist the drug being administered. This unfortunate dilemma often leads to far more serious illness and even death, and is being reported as increasing in frequency at an alarming rate making it a major health concern.

Articles of such reports have been a mainstay in newspapers, news broadcasts, non-techical magazines, and other general public publications for at least the last decade. The majority of people on the street are aware of this health care crisis, not to mention practitioners of the art.

Drug companies are spending 100's of millions of dollars enlisting a broad array of researchers in hopes of finding solutions to drug-resistant bacteria with only disappointing results.

Applicant submits that the written specification is enabling to practitioners of the art to make and use the invention, to ascertain the scope of the invention, that the Applicant was in possession of the invention at the time the application was filed, and that all requirements related to species/genus identification are satisfied in view of the prior Examiner cited Fujikawa v. Wattanasin, 9 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) and In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Further, that in the interest of being concise, the specification need not, and should not devote space to defining terms and phases already well understood to practitioners of the art.

### 4. <u>AMENDMENT OF CLAIMS IN RESONSE TO REJECTION OF CLAIMS UNDER 35 USC SECTION 112 SECOND PARAGRAPH.</u>

Claims 1, 4, 5, & 7 were rejected as being indefinite for failing to particularly point out, and distinctly claim the subject matter which applicant regards as the invention with use of the phrase "or an equivalent".

This rejection is avoided by amendment of the claims.

The phrase "or an equivalent" has been deleted from the aforementioned claim(s) language without prejudice, and without disclaimer of the subject matter or scope involved in response to Examiner requirement

# 5. TRAVERSE OF REJECTION OF CLAIM 4 UNDER 35 USC SECTION 102

Claims 4 was again rejected as being anticipated by Yamaguchi et. al., or Dorman et. al., who reported limited antibacterial activity in vitro of piperine, and volatile oils of black pepper respectively.

This rejection is yet again traversed.

Applicant shall yet again reiterate that neither piperine, nor volatile oils of pepper constituent "phytoalexins" as in claim 4. Examiner assertion that these constitute identical chemical compositions is entirely unfounded.

Therefore this rejection should be withdrawn.

The invention as claimed is therefore novel, as the cited references fail to identify all elements of the invention as claimed, and should be withdrawn and the claims allowed.